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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,179	06/29/2000	Yuan Chang	45185-CA/JPW/SHS	1263

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EXAMINER	
DAVIS, KATHARINE F	

ART UNIT	PAPER NUMBER
1636	6

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/607,179	CHANG ET AL.	
	Examiner	Art Unit	
	Katharine F. Davis	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 4, 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-49* is/are pending in the application.

4a) Of the above claim(s) *44-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice To Comply* .

DETAILED ACTION

This Office Action is in response to the application (with Preliminary Amendment) filed June 29, 2000 and the Response to the Restriction Requirement filed September 4, 2001. Claims 1-42 have been cancelled. Claims 43-49 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 4 is acknowledged. Applicant maintains that Groups I and II do not define patentably distinct inventions as the antibody of Group II binds to the peptide of Group I and is thus a single inventive concept. Inventions are unrelated (patentably distinct) if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The peptide of Group I and the antibody of Group II each have distinct chemical and physical structures and each can be used in separate applications. Applicant further maintains that it would not be a serious burden on the Examiner to search both groups. However a search of the prior art for the peptide of Group I would not necessarily encompass any antibody to the peptide. A prior art search encompassing both Groups would clearly require a larger search using more search terms and thus an additional volume of possible art to review than would a prior art search of one group. This constitutes a burden on the Examiner. Therefore, Applicant's arguments are not found to be persuasive. The requirement is still deemed proper and is therefore made **FINAL.**

Claims 44-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The following is in regard to the IDS filed on October 11, 2001.

A copy of US Patent 5,306,709 was submitted with the IDS and was listed on the transmittal letter, however this patent was not listed on the PTO-1449 form. Applicant should clarify that this patent is to be included with this IDS.

The document by Saiag *et al.* (Ann Der Ven 122:551-557 1995) was not considered by the Examiner because it is in the French language and no English language abstract or explanation of relevance was submitted with the document.

The following are noted as duplicate citations: Cesarman *et al.* (FASEB J9; A973 1995), Chang *et al.* (Science 266:1865-1869 1994), Jahan *et al.* AIDS Research Human Retrovirology 5:225-231 1989), Su *et al.* (J Formosan Med 95:13-18 1996), Chang (Letter to the Editor, Science 267:1079 1995), Cohen (Science 266:1803-1804 1994), Karp *et al.* (Nature Med 1:309-320 1995), McGrath *et al.* (J AIDS Human Retorvirology 8:379-385 1995), Relman (New

England J Med 332:463-464 1995), Rubin (Letter to the Editor Science 267:157-158 1995) and Russo *et al.* (PNAS 93(25):14862-14867 1996).

Specification

The specification contains nucleotide and/or amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons set forth herein and on the attached Notice To Comply. The sequences in Figure 6 and the sequences on page 148 are not identified with SEQ ID NOS. If these sequences are not included in the originally filed sequence listing they must now be included in a substitute sequence listing (both in computer-readable and paper forms). Additionally, the originally filed paper copy of the Sequence Listing is missing pages 214, 216, 219 and 224. Applicant must provide a substitute paper copy and a computer readable copy of the Sequence Listing and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). A full response to this Office action must include a complete response to the requirement for a new Sequence Listing.

The specification contains duplicate copies of page 84, one copy has been deleted by the Examiner.

Page 27 (lines 28-29, 35-37) of the specification contains an outdated address for the ATCC. Page 91, line 17 of the specification contains unclear text. Page 134 (lines 6, 9,24,30 and

37) of the specification contains extraneous writing. Substitute corrected pages 27, 91 and 134 are required with a statement that no new matter is being added to the specification.

Claim Objections

Claim 43 is objected to because of the following informality: line 4 recites the term Kaposis'. The correct term should be Kaposi's. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43 and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is based on the Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 64, Number 244, Pages 71427-71440). Claim 43 is drawn to an isolated peptide encoded by a nucleic acid which is at least 30 nucleotides in length and has a sequence which uniquely defines a herpesvirus associated with Kaposi's sarcoma, which herperesvirus is present in and recoverable from the HBL-6 cell line (ATTC Accession No. CRL 11762). Claim 49 is drawn to a composition comprising the peptide of claim 43 and a

carrier. These are genus claims encompassing any 30 nucleotide sequence (encoding any isolated peptide) of the entire genome of a herpesvirus associated with Kaposi's sarcoma. Although the instant specification refers to many sequences of a herpesvirus associated with Kaposi's sarcoma (for example: SEQ ID NO:1 page 19, ORF'S on pages 20-21, KS330BAM and KS627BAM, page 95), there are no examples of any specific 30 nucleotide sequence. The disclosure of many sequences of a herpesvirus associated with Kaposi's sarcoma is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision the complete structure of any 30 nucleotide sequence based on the disclosed sequences. Additionally, there is no description of a representative number of species by partial structure and a function which correlates with structure as there is no disclosure of the specific 30 nucleotide sequence(s) which would encode the claimed isolated peptide(s). Therefore, the specification does not describe the claimed isolated peptide(s) and/or sequence(s) in such full, clear, concise and exact terms so as to indicate that applicant had possession of this isolated peptide(s) and/or sequence(s) at the time of filing of the instant application. Thus, the written description requirement has not been satisfied.

Claim 43 is drawn to a specific cell line, HBL-6. Because it is not clear that the identical cell line is freely available or can be reproducibly isolated from nature a biological deposit of the cell line for patenting purposes is required. Although the claim and instant specification indicate that a deposit has been made (ATCC Accession No. CRL 11762, page 27), no statement has been submitted which indicates that all restrictions on availability of the deposited cell line will be removed upon issuance of a patent.

The requirements for description and enablement may be met by depositing the cell line in a recognized depository. If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant or a statement by an attorney of record over his or her signature and registration number, stating that the specific material has been deposited under the Budapest Treaty and that the material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the requirements of 37 CFR 1.801-1.809 (see Federal Register, Vol. 54, No. 161, issued August 2 1989), Applicant may provide assurance of compliance by an affidavit or declaration or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
(d) the deposit will be replaced if it should ever become inviable.

Applicant must furthermore submit a viability statement consisting of:

(1) the name and address of the depository;
(2) the name and address of the depositor;
(3) the date of deposit;
(4) the identity of the deposit and the accession number given by the depository;
(5) the date of the viability test;
(6) the procedures used to obtain a sample if the test is not done by the depository; and
(7) a statement that the deposit is capable of reproduction.

A viability statement is not required for deposits made under the Budapest Treaty.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 recites the phrase "...has a sequence..." It is unclear if the nucleic acid or the peptide defines the herpesvirus, thereby rendering the claims indefinite.

Conclusion

Claims 43 and 49 are rejected. Claims 43 and 49 are free of the prior art because the prior art does not teach or suggest an isolated peptide encoded by a nucleic acid which is at least 30 nucleotides in length and has a sequence which uniquely defines a herpesvirus associated with Kaposi's sarcoma, which herperesvirus is present in and recoverable from the HBL-6 cell line (ATTC Accession No. CRL 11762). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott can be reached on (703) 308-4003. The fax phone numbers for the organization where this application or proceeding is

assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry concerning the formalities of this application should be directed to Patent Analyst Dianiece Jacobs whose telephone number is (703) 305-3388. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Katharine F. Davis
November 18, 2001

DAVID GUZO
PRIMARY EXAMINER

file

Application No.: 09/607,179

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set by the Office communication to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: Please see "specification" section of the attached Office Action

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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